UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

UNITED STATES OF AMERICA, Plaintiff, v. ELK PHARMACY, INC., LARRY IRWIN, SUSAN BAKER, S. JASON COUCH, BETH PENCE, and LORI WYBLE, Defendants.	)	No. 24-CV-1006

COMPLAINT

The United States of America, by and through its undersigned attorneys, complains and alleges as follows:

INTRODUCTION

1. From 2000-2022, more than 37,000 North Carolinians lost their lives to drug overdose. In 2018 and 2019, Surry County had some of the highest rates of opioid overdose emergency visits in North Carolina, consistently ranking in the top five counties statewide. In 2018, there were 122.2 opioid prescriptions dispensed for every 100 people in Surry County, the third-highest rate in the state. Even now, prescription opioid abuse and diversion remain a public health emergency.

2. As the front-line dispensers of controlled substances, pharmacists play a critical role in the ongoing battle against opioid abuse and diversion. As

a result, under the Controlled Substances Act ("CSA"), pharmacists have a responsibility to ensure that the prescriptions they fill are legitimate and to identify and address any "red flags" apparent from the patient, the prescription, or the prescriber.

3. Between 2016 and at least 2019, Elk Pharmacy, Inc. ("Elk Pharmacy") and its pharmacists failed to consistently fulfill this role and uphold their obligations under the CSA. Instead, Elk Pharmacy filled prescriptions for opioids and other potentiating drugs while disregarding red flags suggesting that the prescriptions were being abused or diverted, or otherwise posed a significant risk of patient harm.

PARTIES

4. Plaintiff is the United States of America ("United States").

5. Defendant Elk Pharmacy is a corporation organized under the laws of North Carolina, with its principal place of business at 116 E. Main Street, Elkin, North Carolina.

6. At all times relevant to the allegations herein, Elk Pharmacy was registered by the U.S. Drug Enforcement Administration (the "DEA") as a Retail Pharmacy under registration number AE6893374 and was engaged in the business of operating a retail pharmacy in Elkin, North Carolina.

7. Defendant Larry Irwin ("Irwin") is a resident of the Middle District

of North Carolina. At all times relevant to the allegations herein, Irwin was a pharmacist duly licensed by the North Carolina Board of Pharmacy. Irwin is the owner of Elk Pharmacy and also works as a pharmacist at Elk Pharmacy.

8. Defendant Susan Baker ("Baker") is a resident of the Middle District of North Carolina. At all times relevant to the allegations herein, Baker was a pharmacist duly licensed by the North Carolina Board of Pharmacy and worked as a pharmacist at Elk Pharmacy.

9. Defendant S. Jason Couch ("Couch") is a resident of the Middle District of North Carolina. At all times relevant to the allegations herein, Couch was a pharmacist duly licensed by the North Carolina Board of Pharmacy and worked as a pharmacist at Elk Pharmacy.

10. Defendant Beth Pence ("Pence") is a resident of the Middle District of North Carolina. At all times relevant to the allegations herein, Pence was a pharmacist duly licensed by the North Carolina Board of Pharmacy and worked as a pharmacist at Elk Pharmacy.

11. Defendant Lori Wyble ("Wyble") is a resident of the Middle District of North Carolina. At all times relevant to the allegations herein, Wyble was a pharmacist duly licensed by the North Carolina Board of Pharmacy and worked as a pharmacist at Elk Pharmacy.

JURISDICTION AND VENUE

12. This is an action to enforce the provisions of the CSA, 21 U.S.C. § 801 *et seq*. This Court has subject-matter jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c)(1)(A), 843(f)(2), and 882(a), as well as 28 U.S.C. §§ 1345 and 1355.

13. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b)(1) and (b)(2) because this is the district in which all the Defendants reside and where a substantial part of the events or omissions giving rise to the claim occurred. Venue is also proper pursuant to 28 U.S.C. § 1395(a) because this is an action for recovery of a pecuniary fine or penalty and this is the venue where the action accrued and where the Defendants are found.

LEGAL BACKGROUND

14. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. It is unlawful to manufacture, distribute, or dispense any controlled substance except in a manner authorized by the CSA or its implementing regulations.

15. Under the CSA, controlled substances are categorized into five schedules based on several factors, including whether they have a currently accepted medical use in treatment in the United States, the potential for abuse, and the likelihood that abuse will cause dependence.

16. Schedule II controlled substances have a currently accepted medical use in the United States, or a currently accepted medical use with severe restrictions. Yet these substances also have a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2). Examples of Schedule II controlled substances include opioid-based painkillers such as oxycodone and hydrocodone.

17. Schedule III controlled substances have a potential for moderate physical dependence or high psychological dependence, but less abuse potential than Schedule II substances. *See* 21 U.S.C. § 812(b)(3). Examples of Schedule III controlled substances include buprenorphine or products containing less than 90 milligrams of codeine.

18. Schedule IV controlled substances may lead to physical or psychological dependence when abused, but the potential for abuse is less than Schedule III substances. *See* 21 U.S.C. § 812(b)(4). Examples of Schedule IV controlled substances include alprazolam and diazepam.

19. To prevent the diversion of controlled substances, the CSA imposes requirements for the distribution and dispensing of these drugs. Among other requirements, pharmacies must register with DEA before distributing or dispensing controlled substances. *See* 21 U.S.C. § 822(a). Once registered, a pharmacy, as well as its agents and employees, are only permitted to distribute

or dispense controlled substances to the extent authorized by their registration and in conformity with the CSA. *See* 21 U.S.C. § 822(b).

20. The CSA defines dispensing to mean delivering a controlled substance to an ultimate user (*e.g.*, a patient) by, or pursuant to a lawful order of, a practitioner (*i.e.*, a prescription). *See* 21 U.S.C. § 802(10). Distributing means delivering a controlled substance other than by dispensing or administering (which is direct application of a drug to a patient). *See id.* §§ 802(11); 802(2)(A).

21. Among its other provisions, the CSA and its implementing regulations limit when a controlled substance may be dispensed pursuant to an oral or written prescription. *See* 21 U.S.C. § 829. Under 21 C.F.R. § 1306.04(a), a prescription for a controlled substance is valid only if it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Along with the prescribing practitioner, a pharmacist considering whether to fill a prescription bears a "corresponding responsibility" to ensure "the proper prescribing and dispensing of controlled substances." *Id.* Any "person knowingly filling" a prescription that is not issued in the usual course of professional treatment "shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*; *see also id.* §§ 1300.01, 1306.02 (defining

"person" to include individuals or any legal entity).

22. A pharmacist may only fill a controlled substance prescription while "acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. Among other things, acting in the usual course of pharmacy practice includes compliance with all relevant state laws and regulations. In North Carolina, a pharmacist "shall not fill or refill a prescription order if, in the exercise of professional judgment, there is or reasonably may be a question regarding the order's accuracy, validity, authenticity, or safety for the patient." 21 N.C. Admin. Code § 46.1801(b).

23. In assessing whether a prescription is issued for a "legitimate medical purpose," a pharmacist looks to see whether the prescription or patient presents "red flags," or warning signs that create a reasonable suspicion that the prescription is not legitimate. "Red flags" may include, for example: the amount or combination of controlled substances prescribed; the abuse potential of those controlled substances; the temporal proximity to other prescriptions filled for the patient; the prescriber's office location relative to the patient's home; the prescriber's prescribing history with the patient, or general prescribing practices; or the behavior of the individual presenting the prescription (such as a request for early refills).

24. When a "red flag" is present, a pharmacist must conduct further and sufficient inquiry to determine whether the prescription is legitimate. A pharmacist must refuse to fill a controlled substance prescription if the pharmacist knows or was willfully blind to the fact that the prescription was not written for a legitimate medical purpose or in the usual course of the physician's professional practice. 21 C.F.R. § 1306.04. Additionally, pharmacists must act in the usual course of professional practice as pharmacists when filling a prescription. 21 C.F.R. § 1306.06. This means that a pharmacist may dispense a controlled substance only in accord with a generally accepted, objective standard of pharmacy practice.

FACTUAL ALLEGATIONS

25. As a retail pharmacy, Elk Pharmacy purchases, stores, and dispenses controlled substances. At all relevant times, Defendants were subject to the registration and dispensing requirements of Part C of the CSA, including 21 U.S.C. § 829.

I. Defendants Ignored Red Flags When Filling Prescriptions.

26. From on or about January 1, 2016 through at least October 1, 2019, Defendants knowingly filled prescriptions for controlled substances that presented significant red flags with respect to the prescriptions' medical legitimacy and/or with respect to whether they were written by a practitioner

in the usual course of professional treatment. Defendants ignored and otherwise failed to take sufficient steps to resolve these red flags before filling the prescriptions.

Red Flag No. 1: High Volumes of Buprenorphine Mono-product

27. Buprenorphine is a critical tool in the safe and effective treatment of opioid use disorder. It is an opioid partial agonist and has unique pharmacological properties that diminish the effects of physical dependency to opioids. Evidence supports that buprenorphine and other medications for opioid use disorder are associated with reduced risk of overdose and overall mortality. But buprenorphine can be misused and diverted, particularly by people who do not have an opioid dependency. To reduce the risk of diversion, many formulations of buprenorphine have added naloxone, an opioid receptor antagonist that blocks the euphoric effects of opioids. As a result, during the relevant time period, the Substance Abuse and Mental Health Service Administration (SAMSHA) advised that the combination buprenorphine-naloxone product was the preferred formulation for all patients, except patients who were pregnant or nursing, or who had a documented allergy to naloxone.

28. Despite this guidance, in 2017, 87% of the buprenorphine prescriptions that Elk Pharmacy filled were for the buprenorphine mono-

product instead of the naloxone-combination product. In 2018, 92% of the buprenorphine prescriptions that Elk Pharmacy filled were for the mono-product. Many of these prescriptions were written by a physician who exhibited other red-flag behavior (including prescribing patients *both* buprenorphine *and* opioids simultaneously and prescribing other dangerous opioid combinations) and who directed his patients to Elk Pharmacy because other pharmacies refused to fill his prescriptions.

29. In 2018, Elk Pharmacy—which is located in a town of 4,000 people—purchased more than 114,218 dosage units of buprenorphine from its supplier. This was twice as much as any other pharmacy in the same zip code.

Red Flag No. 2: Dangerous Drug Combinations/Cocktails

30. Certain combinations of drugs are highly unlikely to serve a legitimate medical purpose, and are known cocktails favored by individuals with drug addictions. For example, certain combinations of opioids and other controlled substances, such as benzodiazepines, muscle relaxers, sedatives, and/or stimulants, can enhance the effects of the opioid, but also increase the risk of overdose. These combinations are well known in the medical and pharmacy community to increase the risk of abuse and overdose, and to pose additional health and safety risks due to side effects.

31. Defendants dispensed combinations of controlled substances,

including high-powered opioids combined with benzodiazepines, muscle relaxers, and/or stimulants, despite significant unresolved red flags regarding the prescriptions' medical legitimacy.

Red Flag No. 3: Long-Term, High-Dose Opioid Prescriptions

32. Opioids are not recommended for long-term treatment of non-cancer pain, such as pain caused by osteoarthritis. During the relevant time period, the CDC Guidelines for Prescribing Opioids for Chronic Pain, published in March 2016, advised that prescribers should be using the lowest effective dosages of opioids, should carefully assess the risks and benefits of dosages above 50 morphine milligram equivalents ("MME") per day, and should avoid dosages above 90 MME per day.[1] The CDC published new guidelines in 2022 that no longer rely on strict MME cutoffs, but the new guidance still reiterates that (1) clinicians should pause and carefully reassess risk-benefit analysis before increasing dosage to 50 MME/day or higher, and (2) additional dosage increases beyond 50 MME/day are progressively more likely to yield diminishing returns in benefits for pain and function relative to risks to patients. The 2022 Guidelines also state that opioids should not be considered

[1] CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. *Recommendations and Reports* 65(1); 1-49 (March 18, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.

first-line or routine therapy for subacute or chronic pain. A high dose should not be routine or standard.

33. Along the same lines, pharmacists exercising their corresponding responsibility during the relevant time period should have, at a minimum, questioned the red flag raised by dosages above 50 MME and should have had substantial justification for dispensing doses exceeding 90 MME, an even more serious red flag. Despite this, Defendants filled long-term prescriptions for opioids well over the CDC's Guidelines, with insufficient or no documentation justifying those dangerous doses.

Red Flag No. 4: "Doctor Shopping" or "Pharmacy Shopping"

34. A person's history of obtaining controlled substances from multiple prescribers is also a red flag that a controlled substance prescription may not have been written for a legitimate medical purpose or in the usual course of professional treatment. For example, a physician may stop writing prescriptions for a person if the physician believes the person is abusing substances, which then leads the person to seek out prescriptions from other providers. Alternatively, a patient could move regularly from doctor to doctor to make it more difficult for any individual prescriber to identify drug-seeking behavior.

35. Seeking prescriptions from multiple prescribers is colloquially referred to as "doctor shopping." Defendants were able to review a person's prescription history, including prescriber information, through North Carolina's Controlled Substance Reporting System. Defendants nevertheless dispensed opioids and other controlled substances to doctor-shopping individuals, including people who had received controlled substance prescriptions from as many as fifteen different prescribers during a three-and-a-half year period.

36. A related red flag is "pharmacy shopping," or moving from pharmacy to pharmacy, for example because one pharmacy has refused to fill a prescription or to conceal obtaining duplicate prescriptions. Reviewing North Carolina's Controlled Substance Reporting System also allowed Defendants to identify when patients engaged in this behavior. Defendants nevertheless dispensed opioids and other controlled substances to these patients without resolving this significant red flag.

Red Flag No. 4: Family Members or Groups of Friends Receiving Similar Prescriptions

37. The presentation of prescriptions for similar combinations of controlled substances by members of the same family, or a group of friends, is also a red flag that the prescriptions may not have been written for a legitimate medical purpose or in the usual course of professional treatment. Defendants

dispensed controlled substances, including similar prescriptions, to individuals of the same family. Similarly, Defendants identified certain doctors whose patients would come to the pharmacy in groups and present identical prescriptions, yet Defendants filled those prescriptions anyway.

Red Flag No. 5: Requests for Early Refills and "Pill Lending"

38. A person's attempt to fill a prescription early—*i.e.*, before their current supply of drugs from a previous prescription is exhausted—is also a red flag that a controlled substance prescription may not have been written for a legitimate medical purpose or in the usual course of professional treatment. Defendants nonetheless dispensed controlled substances to people who requested early refills and exhibited other drug-seeking behavior. Defendants also dispensed controlled substances, including Xanax, to individuals who did not have a valid or current prescription, by "lending" those pills before the patient presented a valid prescription.

II. Defendants Turned a Blind Eye to Doctors They Identified as Suspicious.

39. Elk Pharmacy's employees were aware of two doctors who caused red flag concerns yet filled prescriptions written by those doctors anyway.

40. Elk Pharmacy filled controlled substance prescriptions written by one physician while she was subject to an interim non-practice agreement with

the North Carolina Medical Board that barred her from prescribing controlled substances.

41. In the case of another doctor, Elk Pharmacy filled many prescriptions for his patients even though other pharmacies in the area refused to fill his prescriptions. His patients would request cash pay, claiming they lacked insurance, and groups of friends and couples would approach with identical prescriptions, at the same time. This doctor also claimed to be an addiction specialist, yet prescribed opioids and buprenorphine at the same time, and prescribed dangerous combinations of opioids, benzodiazepenes, and carisoprodol. Employees were aware of these red flags and filled the prescriptions from this doctor anyway.

III. Defendants Filled Prescriptions for Customers Who Exhibited Multiple Red Flags.

42. Defendants' customers often exhibited a combination of the foregoing red flags. The following examples illustrate in detail Defendants' failure to resolve red flags in filling prescriptions for opioids and other dangerous controlled substances.

Individual A

43. Elk Pharmacy, through each of the five individual Defendant pharmacists, filled Individual A's prescriptions for opioids and other controlled substances from January 2016 through September 2019. For more than three

and a half years, Individual A received prescriptions for both oxycodone and morphine ER (later switched to fentanyl), with daily MMEs ranging from 240 to 367.5. During the same time, Individual A was also receiving prescriptions for carisoprodol and alprazolam and a stimulant.

44. Many of the ICD-10 codes listed on Individual A's prescriptions did not support the prescriptions, yet there is no indication Elk ever questioned this long-term multi-drug cocktail or the potential for dangerous drug-drug interactions. For example, one prescriber used the code for opioid dependence to justify an opioid prescription, which pharmacist Defendant Irwin then filled. Another prescriber used a code (among other diagnoses) for diabetic polyneuropathy from Type 1 diabetes, which: (1) is not typically treated with opioids, and (2) was particularly suspect, because Individual A had no record of insulin prescriptions or a diabetes diagnosis in his pharmacy profile. Pharmacist Defendants Wyble, Pence, and Baker all filed fentanyl and/or oxycodone prescriptions between September 2018 and March 2019 notwithstanding this red flag. Individual A's alprazolam prescriptions were also dosed "as needed for sleep" at the same time Individual A was receiving the maximum dose of a prescription sleep aid. Pharmacist Defendants Irwin, Couch, and Wyble all filled these prescriptions.

45. Upon information and belief, Elk Pharmacy and all five

pharmacist Defendants dispensed controlled substances to Individual A without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented at the pharmacy.

Individual B

46. Elk Pharmacy, through each of the five individual Defendant pharmacists, filled prescriptions for Individual B from more than ten different providers from January 2016 through December 2018. Individual B received both oxycodone (30mg six times per day) and oxymorphone ER (30mg three times per day), amounting to daily MME of 540, for more than a year and a half, and received prescriptions for alprazolam and carisoprodol along with those opioids for several months. Oxymorphone ER should not be dosed three times per day, because of how long it acts in the body: Individual B was getting overlapping doses of the medication and was at risk for serious adverse effects.

47. Individual B had more than ten different doctors issuing prescriptions, lived far away from several of the prescribers, and paid out of pocket for several prescriptions, which is another red flag of abuse or diversion. In one month, Individual B received an alprazolam prescription from one doctor, opioid prescriptions from another doctor, and a carisoprodol prescription from a third doctor. Further, in May 2017, Individual B received a prescription for buprenorphine (presumably to treat opioid addiction) from

one prescriber, then nineteen days later, Defendant pharmacist Irwin filled a prescription for oxymorphone from a different prescriber.

48. Upon information and belief, Elk Pharmacy and all five pharmacist Defendants dispensed controlled substances to Individual B without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented at the pharmacy.

Individual C

49. Elk Pharmacy, through each of the five individual Defendant pharmacists, filled prescriptions for Individual C from January 2016 through September 2019.

50. Individual C received a daily MME of 630—seven times the CDC's upper limit—for a year from a prescriber who Elk employees recognized was problematic (and who later lost her DEA registration). In addition to the extremely high quantity, Individual C's oxymorphone ER dosing was incorrect: it should not be dosed more than every 12 hours due to how long it works in the body, yet Individual C's prescription called for 3 times daily, causing overlapping dosage and extremely high risk of respiratory depression. The 630 MME prescriptions, including the incorrect oxymorphone ER dosing, were filled by Defendant pharmacists Irwin, Wyble, Couch, and Baker. Individual C later received oxycodone prescriptions from a purported "addiction medicine"

specialist increasing from 60MME to 180MME by July 2019. At the same time, Individual C was receiving benzodiazepines from multiple different prescribers. In July 2017, Individual C filled prescriptions for four different benzodiazepines at Elk Pharmacy, from three different prescribers. On July 19, 2017, pharmacist Defendant Pence dispensed a 30-day supply of both alprazolam 1mg and triazolam .25mg from a Wilkesboro, NC doctor. Five days later, on July 24, 2017 pharmacist Defendant Couch dispensed a 2-day diazepam prescription from a urologist, and then dispensed a 30-day supply of clonazepam 1mg from a Mt. Airy physician. One of those benzodiazepines—triazolam—is only labeled for short-term use but Individual C was on it for twenty-two months before the pharmacy spoke to the prescriber about the duplicative therapy. The pharmacy also "loaned" Individual C tablets of triazolam in June 2018. In addition to these red flags, Individual C claimed to be allergic to codeine (which would have also meant Individual C was allergic to other medications they were receiving). Individual C also saw multiple different prescribers over four years and traveled significant distances to those providers.

51. Upon information and belief, Elk Pharmacy, including all five individual pharmacist Defendants, dispensed controlled substances to Individual C without taking necessary and sufficient steps to resolve the red

flags raised by the prescriptions presented at the pharmacy.

Individual D

52. Elk Pharmacy, through pharmacist Defendants Pence, Wyble, Couch, and Baker, filled prescriptions for Individual D from July 2017 to March 2019. In particular, Individual D received regular combinations of oxycodone and clonazepam, along with periodic prescriptions for carisoprodol, even though Elk was 25 miles from the patient's home. Pharmacist defendants Couch, Pence, Wyble, and Baker dispensed these prescriptions. Individual D's provider—a doctor who Elk employees recognized as raising red flags—prescribed a stimulant to this patient while the patient was already taking a dangerous combination. Individual D used her insurance for non-controlled medications and some clonazepam and carisoprodol fills, but Individual D paid out of pocket for oxycodone and the other prescriptions. For example, on April 25, 2018, pharmacist Defendant Wyble dispensed both oxycodone and carisoprodol, which Individual D paid for in cash, and Elk also dispensed clonazepam the same day. As another red flag, Individual D twice filled intervening prescriptions for opioids at a chain pharmacy while getting regular prescriptions at Elk Pharmacy. For example, on May 17, 2018, Individual D filled a 6-day prescription for hydrocodone-acetaminophen 5-325 at a chain pharmacy after obtaining a 30-day oxycodone prescription at Elk Pharmacy on

April 25, 2018. Elk Pharmacy filled a 30-day prescription for oxycodone on May 23, 2018, yet had no notes to suggest that they had checked Controlled Substance Reporting System ("CSRS") data and discovered this aberration. In August 2018, Individual D filled a tramadol prescription at another pharmacy amidst routine 30-day oxycodone prescriptions at Elk. Again, Elk had no records showing that they had either checked CSRS or resolved these additional opioid prescriptions. In July 2018, Individual D also received and filled at Elk simultaneous oxycodone and methadone prescriptions (a dangerous combination) from a prescriber 150 miles from home who was not the normal provider.

53. Upon information and belief, Elk Pharmacy, including pharmacist Defendants Pence, Wyble, Couch, and Baker, dispensed controlled substances to Individual D without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented the pharmacy.

Individual E

54. Elk Pharmacy, through each of the five individual Defendant pharmacists, filled prescriptions for Individual E from February 2016 to November 2017.

55. Individual E received high dosages

56. of opioids, along with benzodiazepines, filled at Elk throughout

2016 and 2017, and prescribed by a doctor that Elk had identified as presenting red flag prescriptions. On October 13, 2017, the pharmacy noted that the Individual E's insurance would only cover 75 tablets (a 30-day supply). However, pharmacist Defendant Irwin filled that prescription as well as a 15-tablet prescription that Individual E paid for out-of-pocket; thus, providing the patient with 90 tablets of oxycodone 30mg. On November 2, 2017—20 days later—Individual E received another 90 tablets from Elk, when he should have still had a 10-day supply. Individual E paid for this fill entirely out-of-pocket. On November 30, 2017—28 days later— Individual E received yet another early fill from Elk, for 90 tablets of oxycodone. From October 13 through November 30, 2017, Individual E received 270 tablets of oxycodone 30, when he should only have had 180 tablets.

57. Upon information and belief, Elk Pharmacy and all five pharmacist Defendants dispensed controlled substances to Individual E without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented at the pharmacy.

CIVIL PENALTY LIABILITY
21 U.S.C. § 842(a)(1)

58. The United States re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

59. 21 U.S.C. § 842(a)(1) makes it unlawful for any person subject to

Part C of the CSA to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829. As a DEA registrant and owners-managers of a registrant dispensing controlled substances, respectively, Defendants are subject to Part C of the CSA.

60. Defendants violated 21 U.S.C. § 829 by filling prescriptions for Schedule II, III, or IV controlled substances that also were prescription drugs under the Federal Food, Drug, and Cosmetic Act, outside the usual course of pharmacy practice and not in compliance with their "corresponding responsibility." 21 C.F.R. §§ 1306.04 & 1306.06.

61. Namely, upon information and belief, Defendants filled prescriptions that were not written for a legitimate medical purpose or were written outside the usual course of professional treatment, as evidenced by the numerous red flags Defendants failed to resolve prior to filling such prescriptions.

62. Under 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5, each violation of 21 U.S.C. § 842(a)(1) subjects Defendants to a civil penalty of not more than $25,000.00 for violations occurring on or before November 2, 2015, and not more than $80,850.00 for violations occurring after November 2, 2015.

PERMANENT INJUNCTIVE RELIEF
21 U.S.C. §§ 843(f)(1) and 882(a)

63. The United States re-alleges and incorporates by reference the

foregoing paragraphs as if fully set forth herein.

64. Under 21 U.S.C. § 843(f), the Attorney General of the United States is authorized to seek appropriate declaratory or injunctive relief relating to violations of 21 U.S.C. § 842. More broadly, 21 U.S.C. § 882(a) provides for any violation of the CSA to be enjoined.

65. Based on the violations set forth herein and Defendants' years-long pattern of conduct, the United States requests that the Court enter a permanent injunction prohibiting Defendants from directly or indirectly dispensing, assisting in the dispensing, or otherwise facilitating the dispensing of any controlled substance as defined in the CSA or its implementing regulations, unless dispensing the prescription is in compliance with 21 U.S.C. § 842, 21 C.F.R. §§ 1306.04, 1306.06, or any of the North Carolina statutes and regulations pertaining to the dispensing of controlled substances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter judgment in favor of the United States and against Defendants as follows:

1. Impose civil penalties in an amount to be determined by the Court for each violation of 21 U.S.C. § 842(a)(1) committed by Defendants;

2. Enter a permanent injunction prohibiting Defendants from directly or indirectly dispensing, assisting in the dispensing, or otherwise

facilitating the dispensing of any controlled substance as defined in the CSA or its implementing regulations, unless dispensing the prescription is in compliance with 21 U.S.C. § 842, 21 C.F.R. §§ 1306.04, 1306.06, or any of the North Carolina statutes and regulations pertaining to the dispensing of controlled substances;

3. Award the costs associated with the investigation, prosecution, and collection of the penalties and other relief in this matter; and

4. Award any other relief deemed just by the Court.

Respectfully submitted this 27th day of November, 2024.

SANDRA J. HAIRSTON
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